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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,323	12/20/2004	Masazumi Nishikawa	263192US0PCT	3573

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EXAMINER

YEBASSA, DESTA LETTA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,323	<b>Applicant(s)</b> NISHIKAWA ET AL.	
	<b>Examiner</b> Desta L. Yebassa	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-8 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-8 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/20/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Election/Restriction Amendment***

Acknowledgment is made for the amendments filed 09/22/2005.

The following office action is a responsive to the amendments filed 09/22/2005 in which a provisional election was made with transverse to prosecute the invention of species from formula I, a diacylglyceryl ether-containing composition derived from shark liver oil, in which R1, R2, and R3 are aliphatic hydrocarbon and acyl group

The response has the following effect:

1. Claims 6-8 are prosecuted by the examiner.
2. Claim 5 is withdrawn.

The response is contained herein below:

(a) Because these inventions contain undefined species of R1, R2, and R3 (aliphatic hydrocarbon and acyl groups) of formula I, and the applicant did not provide the specific name of aliphatic hydrocarbon and acyl groups, restriction for examination purposes as indicated is proper.

(b) Claim 1 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/22/2005. Therefore, the amendment is not persuasive and the requirement is still deemed proper.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preventing skin damage, comprising orally administering a composition containing diacylglyceryl ether, does not reasonably provide enablement for a method of preventing skin damage. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The invention is directed to a method of preventing skin damage, comprising orally administering a composition containing diacylglyceryl ether. But, there is no data in the specification to support the asserted utility. The specification does not provide guidance to the person of ordinary skill or one skilled in the art to practice the invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400, (CAFC, 1988) at 1404 where the court set forth the eight factors to be considered when assessing if a disclosure would have required undue experimentation. For this rejection under 35 U.S. C. 112, first paragraph, the following factors are considered:

1. Amount of direction and guidance provided by the inventor.
2. The quantity of experimentation necessary
3. Level of ordinary skill in the art.
4. Existence of working examples.

Art Unit: 1615

5. The state of the prior art.
6. Level of predictability or un predictability in the art.
7. The breadth of the claims.
8. Nature or complexity of the invention.

The invention is directed to a method of preventing or treating skin damage, comprising orally administering a composition containing diacylglyceryl ether. But, there is no data in the specification to support the asserted utility. The specification does not provide guidance to the person of ordinary skill or one skilled in the art to practice the invention. Since the examples disclosed in the specification is directed to a method of preventing or treating skin damage, it is not known how a method of composition as claimed can be administrated to prevent skin damage that may have been already infected a patient. The specification does not provide a guidance to the person of ordinary skill or one skilled in the art to practice the invention. Based on the content of the disclosure, the quantity of the experimentation required to prevent the skin damage and perform the scope of the invention will be burdensome since the working examples is directing to treating and not to preventing skin damage in person not yet infected or infected.

The state of the art is what the prior art knows about the invention. There is no Known art wherein a certain composition is administrated to successfully prevent the skin damage before infection or after infection. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to claimed invention. Since the inventors have not provided the level of

Art Unit: 1615

predictability on how and when a person is exposed or infected; and since the invention is directed to a method of preventing or treating skin damage, comprising orally administering a composition containing diacylglyceryl ether; the standard of prevention has not been met. Thus in the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants. Applicant fails to set forth the criteria that define a method of preventing skin damage. Additionally, applicant fails to provide information allowing the skilled person to ascertain these compositions with out undue experimentation. Therefore, the instant claims do not reasonably provide enablement for a method of preventing skin damage.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Application No. (JP 07-082162) in view of Tanaka et al. (U.S. Patent Number 5,849,309).

JP 07-082162 teaches a dermatic agent for external use exhibiting excellent action to repair the damaged skin and having excellent safety and oxidation stability. Various components used for the repair of the damaged skin are such as triglyceride of fish liver oil, e.g. hydrogenation product of a triglyceride of cod liver oil or shark liver oil, ointment, cream, lotion, an oily component, a powder component, a surfactant, a moisturizer, antiseptics and the like (abstract and machine translation of the text).

Tanaka et al. teaches a skin activators which increase the amount of water-retaining glycosaminoglycans in the skin, effective for activating the skin from the inside, to prevent age-related morphological changes in the skin, typically used as an antiaging cosmetic for the purpose of preventing wrinkles (column 1, lines 65 and column 2, lines 5-10). Tanaka et al. also teaches variety of cosmetic compositions and additives used as skin activators including inorganic pigments, organic pigments, inorganic powders, organic powders, hydrocarbons, silicones, esters, triglycerides, lanolins, waxes, vegetable oils, surfactants, vitamins, antioxidants, preservatives and the like (column 2, lines 55-60).

The primary reference, JP 07-082162, teaches a dermatic agent for external use exhibiting excellent action to repair the damaged skin and having excellent safety and oxidation stability, various components used for the repair of the damaged skin such as triglyceride of fish liver oil, e.g. hydrogenation product of a triglyceride of cod liver oil or

Art Unit: 1615

shark liver oil, ointment, an oily component, and a powder component. The secondary reference, Tanaka et al., teaches a skin activators which increase the amount of water-retaining glycosaminoglycans in the skin, effective for activating the skin from the inside, to prevent age-related morphological changes in the skin, typically used as an anti-aging cosmetic for the purpose of preventing wrinkles, and variety of cosmetic compositions and additives used as skin activators including inorganic pigments, organic pigments, inorganic powders, organic powders, hydrocarbons, silicones, esters, triglycerides, lanolins, waxes, vegetable oils, surfactants, vitamins, antioxidants, preservatives.

The prior arts recited as combined teach all the limitations of the instant claims. Therefore, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to select any of the triglyceride of fish liver oil, e.g. hydrogenation product of a triglyceride of cod liver oil or shark liver oil, ointment, cream, lotion, an oily component, a powder component, a skin activators, inorganic pigments, organic pigments, inorganic powders, organic powders, hydrocarbons, triglycerides, lanolins, waxes, vegetable oils, surfactants to form a composition of dermatic agent for external use exhibiting excellent action to repair the damaged skin. Thus the invention as whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.



Art Unit: 1615


***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
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